

# EXHIBIT P

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

Hon. Robert B. Kugler

Hon. Joel Schneider

Civil No. 1:19-md-2875-RBK-JS

**MYLAN'S OBJECTIONS TO PLAINTIFFS' THIRD-PARTY SUBPOENAS**

Defendants Mylan N.V., Mylan Laboratories Limited, and Mylan Pharmaceuticals Inc. (collectively, "Mylan") hereby object to Plaintiffs' third-party subpoenas<sup>1</sup> served on Mylan's ostensible contractors and vendors.<sup>2</sup>

**GENERAL OBJECTIONS AND RESERVATION OF RIGHTS**

Mylan raises the following General Objections with regard to all of the third-party subpoenas issued by Plaintiffs. Mylan reserves the right to fully brief the issues in these Objections in the event that Plaintiffs move to overrule Mylan's objections, or to the extent Mylan must move to quash or modify Plaintiffs' Third-Party Subpoenas.

**1. Plaintiffs Failed to Give Prior Notice to Mylan**

As a threshold matter, the domestic and foreign subpoenas are facially and procedurally defective insofar as Plaintiffs ignored the prior notice requirement of Rule 45, which states "[i]f the subpoena commands the production of documents, electronically stored information, or tangible things or the

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<sup>1</sup> The subpoenas directed to Mylan's purported domestic vendors relate to the following entities: Avantor, Cambrex, Eurofins Lancaster Laboratories, Inc., Galbraith Laboratories, ICON Laboratory Services, Inc., and Stericycle. The subpoenas directed to Mylan's purported foreign vendors relate to the following entities: Amsal Chem Pvt., Lantech Pharmaceuticals, Snehaa Solvents, and Vega Lifesciences PVT. LTD.

<sup>2</sup> Mylan has standing to challenge these third-party subpoenas because the subpoenas seek the production of Mylan's commercially sensitive and confidential proprietary/trade secret business information.

inspection of premises before trial, then before it is served on the person to whom it is directed, a notice and a copy of the subpoena must be served on each party.” FED. R. CIV. P. 45(a)(4). As the U.S. District Court for the Eastern District of Pennsylvania explained:

A party issuing a subpoena to a non-party for the production of documents during discovery must provide prior notice to all parties to the litigation. *The term “prior notice” means notice prior to service of the subpoena on the non-party*, rather than prior to document production. The purpose of prior notice is to afford other parties an opportunity to object to the production or inspection and to obtain the materials at the same time as the party who served the subpoena.

*Coleman-Hill v. Governor Mifflin Sch. Dist.*, 271 F.R.D. 549, 552 (E.D. Pa. 2010) (citations omitted) (emphasis supplied). Here, Plaintiffs served Mylan with copies of the subpoenas only *after* the subpoenas were “in the process of being served on the [non-]parties identified therein.” (See Ex. A, Oct. 16, 2020 email serving subpoenas.)<sup>3</sup> Although Plaintiffs provided Mylan with the list of entities to be served prior to service, Plaintiffs failed to provide any information regarding the specific requests for documents and information that were ultimately served. This is in direct violation of Rule 45, and renders the subpoenas void and unenforceable. See *Fla. Media, Inc. v. World Publ’ns, LLC*, 236 F.R.D. 693, 695 (M.D. Fla. 2006) (finding subpoenas issued to 80 non-parties void and unenforceable where the plaintiff failed to give prior notice to the defendant); see also *Coleman-Hill*, 271 F.R.D. at 555-56 (granting the defendant’s request for admonishment and admonishing the plaintiff’s counsel for failing to serve copies of non-party subpoenas *before* serving them on third-parties, which would have afforded “the opportunity to lodge objections.”).

## 2. The Subpoenas Command Compliance Beyond the Geographical Limits of Rule 45

Rule 45 provides that a subpoena may command the “production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person

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<sup>3</sup> The subpoenas indicate that they were served on the third-parties the day before Mylan was even given notice.

resides, is employed, or regularly transacts business in person.” FED. R. CIV. P. 45(c)(2)(A). Plaintiffs have directed subpoenas to Avanor in New Jersey, to Cambrex in New Jersey, to Eurofins Lancaster Laboratories, Inc. in Pennsylvania, to Galbraith Laboratories in Tennessee, to ICON Laboratory Services, Inc. in New York, and to Stericycle in Illinois. (*See generally*, Ex. A.) None of these entities are located within 100 miles of Plaintiffs’ designated place of compliance at 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55401. Of course, the same is obviously true for the four Mylan vendors who are the subjects of the foreign subpoenas, all of whom are located in India. (*See generally*, Ex. B.) It is well-settled that “a subpoena that purports to compel production beyond the geographical limits specified in Rule 45(c) does not comply with the requirements of the Rule.” *Uniloc USA, Inc. v. Apple Inc.*, No. 19-cv-1692, 2020 WL 6262349, at \*2 (N.D. Cal. Oct. 23, 2020) (denying Apple’s motion to compel compliance with non-party subpoena). Therefore, because Plaintiffs’ subpoenas seek to compel compliance at a location more than 100 miles from where these entities are headquartered, they are facially invalid. *See AngioScore, Inc. v. TriReme Med., Inc.*, No. 4:12-cv-3393, 2014 WL 6706873, at \*1 & n.1 (N.D. Cal. Nov. 25, 2014) (holding that a Rule 45 subpoena specifying the place of compliance as more than 100 miles from nonparty’s headquarters was “invalid on its face”).

### **3. The Foreign Subpoenas Are Invalid Because Rule 45 Does Not Extend to Foreign Entities**

Plaintiffs’ third-party subpoenas issued to foreign entities located in India are facially invalid and are an improper attempt to extend Rule 45 extraterritorially. Foreign entities who are not party to a case are well beyond the jurisdiction of a United States District Court’s subpoena power. *See, e.g., Viasat, Inc. v. Space Sys./Loral, LLC*, No. 3:13-cv-2074, 2014 WL 12577593, at \*5 (S.D. Cal. June 30, 2014) (concluding that a non-party Canadian company “is not a United States national or resident and therefore cannot be served with a subpoena under Rule 45.”);

*Litetronics Int'l Inc. v. Technical Consumer Prods., Inc.*, No. 3:03-cv-5733, 2006 WL 2850514, at \*2 (N.D. Ill. Sep. 28, 2006) (noting that a Chinese corporation is beyond the jurisdiction and subpoena power of the Court and suggesting that the parties investigate whether the Hague Convention would be appropriate); *see also In re: Benicar (Olmesartan) Prod. Liab. Litig.*, No. 1:15-md-2606, 2016 WL 5817262, at \*3 n.13 (D.N.J. Oct. 4, 2016) (Schneider, J.) (recognizing that “Rule 45 does not authorize the service of a subpoena on a foreign witness[,]” and that “[t]he scope of Rule 45 is limited to service in the United States or service of a subpoena on a United States national or resident in a foreign country.”).

Since the Indian entities from whom Plaintiffs request documents are not within this Court’s jurisdiction, and because India is a party<sup>4</sup> to the Hague Convention on the Taking of Evidence Abroad,<sup>5</sup> service must be made through its provisions. *See GMA Accessories, Inc. v. Solnicki*, No. 1:07-cv-3219, 2010 WL 3749213, at \*1 (S.D.N.Y. Sept. 24, 2010) (finding subpoena to non-party was not properly served and stating that “[t]he Hague Convention’s procedures for service are mandatory here because Argentina, the country in which [the plaintiff] sought to serve the subpoena on [the non-party], is a signatory to that Convention . . . and this Court has not ordered any alternative” service method).

#### **4. The Subpoenas Seek Mylan’s Confidential, Trade Secret, and Proprietary Business Information**

Plaintiffs’ subpoenas seek the production of documents that contain Mylan’s confidential, trade secret, and proprietary business information, including Mylan’s contracts, manufacturing processes and methods, pricing information, business strategies, and production goals. Although

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<sup>4</sup> *See* <https://www.hcch.net/en/states/authorities> (last visited Oct. 28, 2020).

<sup>5</sup> *See* Hague Conference, The Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, Mar. 18, 1970, available at <https://www.hcch.net/en/instruments/conventions/full-text/?cid=82>

the Court has entered a Confidentiality and Protective Order (Dkt. 139) that contains provisions related to third-party subpoenas, the Plaintiffs do not have *carte blanche* to seek Mylan's confidential information from third parties, particularly where that information is not discoverable under the Federal Rules of Civil Procedure, nor admissible pursuant to the Federal Rules of Evidence. Indeed, "[t]he mere presence of a protective order does not by itself require disclosure of any kind. Courts have routinely found that a protective order is insufficient protection against unnecessary disclosure of confidential information to the requesting party." *Lakeview Pharmacy of Racine, Inc.*, 2017 WL 4310221, at \*9. Mylan objects to all of Plaintiffs' third-party subpoenas on this basis.

#### **5. The Subpoenas are Facially Overbroad**

Each of Plaintiffs' third-party subpoenas, whether directed to entities who purportedly do business with Mylan, or to entities purportedly associated solely with other Defendants, defines the term "defendants" to include all of the Manufacturer Defendants in this litigation. Significantly, Plaintiffs document requests are styled to seek the production of documents from each third-party related to "any defendant." Plaintiffs are not entitled to request Mylan's confidential information from third parties where Plaintiffs have no good faith basis to assert that the third-party had any relationship with Mylan with respect to valsartan sold in the U.S. market. Mylan objects to all of Plaintiffs' third-party subpoenas on this basis.

#### **6. The Subpoenas Directed to Amsal Chem Pvt. and Eurofins Lancaster Laboratories, Inc.**

After reasonable investigation, Mylan does not believe that these entities had any involvement with regard to the manufacture, sourcing of raw materials, testing, or recalls associated with valsartan products sold in the United States. Therefore, Mylan objects to these two subpoenas in their entirety.

### SPECIFIC OBJECTIONS

Each of Plaintiffs' third-party subpoenas contains identical document requests directed to each entity. In order to avoid duplication, Mylan provides the following global objections to the Plaintiffs' specific requests, which apply to all of the subpoenas directed to third parties with whom Mylan purportedly conducts business.

#### Contracts

- 1. Documents sufficient to show when You were first retained by any Defendant with which you had a contractual relationship that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, public relations relating to the ARB drug recalls, or recall management.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs, not just valsartan products, as Mylan has not recalled any ARB other than valsartan products for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

- 2. Any document evidencing the scope or nature or work you performed for any Defendant that related in any way to ARB drugs, cGMP compliance, FDA advocacy or communication, ARB drug recalls, recall processing, product preservation of destruction, product testing, public relations or crisis management relating to the ARB drug recalls, or recall management.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs, not just valsartan products, as Mylan has not recalled any ARB other than valsartan products for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

3. **Any contracts executed by you on behalf of any Defendant for services to be provided by any other third parties (such as additional cGMP consultants, outside laboratories, regulatory consultants or the like) related to the manufacture of any ARB drug.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs, not just valsartan products, as Mylan has not recalled any ARB other than valsartan products for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

#### **Communications with Relevant Parties**

1. **All non-privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs other than valsartan products and all nitrosamines other than NDEA, as Mylan has not recalled any valsartan product for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

2. **A log of all privileged communications between you and any Defendant regarding the FDA's investigation into the nitrosamine contamination, including the following fields of information:**
  - a. **Date**
  - b. **Recipients and/or Senders of the Communication**
  - c. **General Subject Matter**
  - d. **Basis of Privilege**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs other than valsartan products and all nitrosamines other than NDEA, as Mylan has not



recalled any valsartan product for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, and to valsartan marketed and sold in the United States. Mylan further objects to the extent this request calls for the production of documents or information protected by the attorney-client privilege, the attorney work product doctrine, or any other potentially applicable privilege or doctrine.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

#### **ANDA and DMF File Documents**

**1. All communications between You and any Defendant regarding the filing or supplementation of any Drug Master File relating to any ARB drug.**

**OBJECTION:** Mylan objects to this request to the extent it seeks documents duplicative of what Mylan previously in core discovery with regard to DMF No. 018253, ANDA 090483, ANDA 090866, and ANDA 078020. Mylan further objects to this request as overly broad, unduly burdensome, and not proportionate to the needs of the case in that it seeks information related to all ARB drugs, not the valsartan products that Mylan recalled for the potential presence of NDEA at trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

#### **Nitrosamine Contamination**

**1. All communications between you and any Defendant relating to nitrosamines.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information relating to all nitrosamines, rather than being limited to NDEA, as Mylan has not recalled any valsartan product for the potential presence of any impurities other than NDEA at trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**2. All communications between you and any Defendant concerning any toxicology assessment.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information regarding toxicology assessments regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery. Mylan further objects to this request on the ground that it is ambiguous insofar as "toxicology assessment" is undefined.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**3. All communications between you and any other person, including former or current FDA employees regarding any Defendant, or the nitrosamine contamination.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks information on any Defendant regardless of whether those communications are related valsartan or another ARB drug at issue in this litigation. Mylan further objects to this request on the ground that it seeks communications relating to all nitrosamines, rather than NDEA, as Mylan has not recalled any valsartan product for the potential presence of any impurities other than NDEA at trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**4. All documents received by you from any Defendant regarding the nitrosamine investigation, warning letter, and/or inspections of the any facility used to produce any ARB API, any finished dose ARB drug, or any solvent used in manufacturing of any ARB drug.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information regarding the "nitrosamine investigation" and warning letters and inspections of any API manufacturing and finished dose facility, regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery. Mylan further objects to this request to the extent it seeks Mylan's confidential and commercial proprietary business information.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**5. All reports and/or draft reports provided to you regarding the nitrosamine investigation.**

**OBJECTION:** This request is overly broad and seeks irrelevant information regarding the “nitrosamine investigation” and, is not limited to investigations related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court’s rulings on macro discovery, and the needs of this case.

**6. All draft reports edited by you for comment and provided to any Defendant.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and is limitless in its scope and subject matter in that it seeks draft reports related to any drug and for any purpose, regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court’s rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court’s rulings on macro discovery, and the needs of this case.

**7. All documents relating to any CAPA, risk assessment, or toxicology assessment relating to nitrosamine contamination, any ARB drug, or cGMP compliance.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information as it purports to seek documents related to any and all CAPAs, risk assessments, or toxicology assessments related to any ARB drug or cGMP compliance irrespective of whether that information has any relation to the formation or detection of trace amounts of NDEA in Mylan’s valsartan products, the only ARB drugs which Mylan has recalled.. Therefore, this request goes beyond the scope of the Court’s rulings on macro discovery. Mylan further objects to this request on the ground that “CAPA,” “risk assessment,” and “toxicology assessment” are not defined.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court’s rulings on macro discovery, and the needs of this case.

**8. All testing protocols used by you to test for the presence of nitrosamines in any drug.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to all testing protocols regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan

has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**9. All drafts, notes, and final reports relating to any audit you conducted of a Defendant relating to nitrosamines in any ARB API or Finished Dose drug.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to all drafts, notes, and final reports regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**10. All documents or communications relating to nitrosamine testing of any drug.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to nitrosamine testing of any drug regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**Recall-Related Documents**

**1. All documents relating to the decision on whether to recall or not to recall any ARBs API.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to recall determinations of any ARB regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**2. All documents and communications relating to the destruction and/or disposal of any ARB drugs or API.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to the destruction and disposal of any ARB regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**3. All draft and final communications relating to recall letters or notices relating to ARB drugs or API sent to patients, customers, physicians, pharmacies, third-party payors, and distributors.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to recall letters or notices of any ARB regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**4. All return authorization documents and/or communications received by You related to any and all Sartan products.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to return authorizations and communications regarding of any ARB, or "Sartan products" regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**Quarantine and/or Destruction**

**1. All documents and/or communications concerning the storage of recalled and/or withdrawn ARB products or API.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to the storage of any recalled and withdrawn ARB regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**2. All documents and/or communications concerning the preservation of contaminated, recalled, and/or withdrawn ARB products or API.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to the preservation of any contaminated, recalled, and withdrawn ARB regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**3. All documents and/or communications concerning the method of disposing or destroying ARB products or API.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to the method of disposing or destroying any ARB regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**4. All documents and/or communications pertaining to the testing of any recalled and/or withdrawn ARB products or API and results of such testing.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to the testing of any recalled and withdrawn ARB regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.



Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**5. All destruction certifications created related to any ARB products or API.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to the destruction certificates related to any ARB regardless of whether they are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**Communications with the FDA**

**1. All agendas and/or memoranda related to meetings (in person, telephonic, or otherwise) and/or teleconferences had with you, and officials with the FDA regarding any ARB API or finished dose drug, nitrosamine contamination, and/or recall.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related communications with FDA related to any ARB regardless of whether such communications are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**2. All notes taken during any meeting and/or teleconference had with the FDA relating to any ARB ANDA or DMF held by any Defendant and/or the nitrosamine contamination more generally.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related communications with FDA related to any ARB regardless of whether such communications are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**3. All communications made between you and the FDA relating to any ANDA or DMF for any ARB held by any Defendant and/or the nitrosamine contamination more generally.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related communications with FDA related to any ARB regardless of whether such communications are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**4. All communications sent to or from You and anyone employed by the FDA related to the toxicological assessment of NDMA and/or the nitrosamine impurities.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related communications with FDA related to any ARB regardless of whether such communications are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**5. All communications between You and the FDA regarding inspections of any Relevant Party's manufacturing facilities where ARB API, Finished Dose ARB drugs, or solvents used to make ARB drugs or API is manufactured, and the FDA's Warning Letter, including all documents requesting a Type B Meeting.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related communications with FDA related to any ARB regardless of whether such communications are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**6. Documents sufficient to show all meetings, and/or verbal communications had between You and the FDA regarding the Nitrosamine contamination, including calendar entries, meeting requests, and/or notes.**



**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related communications with FDA related to any ARB regardless of whether such communications are related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

#### **Testing Data**

**1. Copies of all testing provided to you by any Defendant related to the testing of product for nitrosamine contamination.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to the testing of any product for nitrosamine contamination regardless of whether it is related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**2. All testing conducted by you, including AMES testing, DEREK testing and the like related to the nitrosamine contamination of any Defendant's drugs.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to the testing of "any of defendants' drugs" product for nitrosamine contamination regardless of whether it is related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**3. Documents sufficient to show the identification of any samples tested by you, including NDC code, lot number and/or batch number.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to the testing of any product for nitrosamine contamination regardless of whether it is related to valsartan containing medications, which are

the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**4. All testing of any ARB Finished Dose drug or ARB API for nitrosamine impurities in your possession, including testing conducted by You, and Relevant Party, or any Third-party Laboratory retained by you.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information related to the testing of any product for nitrosamine contamination regardless of whether it is related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts. Therefore, this request goes beyond the scope of the Court's rulings on macro discovery.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**Solvent Manufacturing, Recovery, and Recycling**

**1. All SOPs relating to the manufacturing, recovery, or recycling of any solvent which was manufactured for or sold to any Defendant for the use in manufacturing API or finished dose products for any ARB.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs, ARBs, API, or finished dose, not just valsartan products, as Mylan has not recalled any ARB other than valsartan products for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, solvents at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**2. Documents identifying the method and manner of solvent manufacturing, recovery, or recycling performed on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs, ARBs, API, or finished dose, not just valsartan products, as Mylan has not recalled

any ARB other than valsartan products for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, solvents at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**3. Documents showing any testing performed by You on solvents manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs, ARBs, API, or finished dose, not just valsartan products, as Mylan has not recalled any ARB other than valsartan products for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, solvents at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**4. Documents identifying the type, amount, and date of any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs, ARBs, API, or finished dose, not just valsartan products, as Mylan has not recalled any ARB other than valsartan products for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, solvents at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**5. Documents identifying the date You delivered any solvents You manufactured, recovered, or recycled on behalf of any Defendant for the use in manufacturing API or finished dose products for any ARB, and the date you delivered same to Defendant.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs, ARBs, API, or finished dose, not just valsartan products, as Mylan has not recalled any ARB other than valsartan products for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, solvents at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**6. Documents identifying the method, manner, frequency, date, and individuals involved in the cleaning of equipment used to manufacture, recover, or recycle solvents for Defendants' use in the manufacturing of API or finished dose products for any ARB.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs, API or finished dose, not just valsartan products, as Mylan has not recalled any ARB other than valsartan products for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, solvents at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

**Toxicology Assessments**

**1. All communications between you and any Defendant regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API or finished dose ARB drug.**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs, API or finished dose, not just valsartan products, as Mylan has not recalled any ARB other than valsartan products for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, solvents at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

- 2. All toxicology assessments, including all draft reports, final reports, redlined reports regarding toxicology assessments conducted with respect to nitrosamine impurities and any ARB drug or API, or any solvent used in the manufacture of such API**

**OBJECTION:** This request is overly broad, unduly burdensome, not proportionate to the needs of the case, and seeks irrelevant information insofar as it seeks documents and information related to all ARBs, API or finished dose, not just valsartan products, as Mylan has not recalled any ARB other than valsartan products for the potential presence of any impurities other than NDEA at trace amounts. Mylan also objects to this request on the grounds that it goes beyond the scope of the Court's rulings on macro discovery, which limited discovery to the specific impurities at issue, solvents at issue, and to valsartan marketed and sold in the United States.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

- 3. All documents provided to you by any Defendant for use in any toxicology assessment(s) related to the nitrosamine impurity in and Defendant's drugs.**

**OBJECTION:** This request is overly broad and seeks irrelevant information regarding "any toxicology assessment" related to an alleged nitrosamine impurity in any of Mylan's medications, and is not limited to toxicology assessments related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

- 4. All other documents, including academic articles, compendia, news reporting, inspection reports, reviewed by you in the preparation of any toxicology assessments conducted with respect to nitrosamine impurities and any Finished Dose ARB drug, ARB API, or any solvent used in the manufacture of such API or finished dose ARB drug.**

**OBJECTION:** This request is overly broad and seeks irrelevant information regarding "any toxicology assessment" related to an alleged nitrosamine impurity in any of Mylan's medications, and is not limited to toxicology assessments related to valsartan containing medications, which are the only medications that Mylan has recalled for the potential presence of NDEA in trace amounts.

Mylan is willing to meet and confer with Plaintiffs in an effort to resolve these objections and modify the subpoenas in a manner consistent with the Federal Rules of Civil Procedure, the Court's rulings on macro discovery, and the needs of this case.

Dated: October 29, 2020

Respectfully submitted,

s/ Clem C. Trischler

Clem C. Trischler

PIETRAGALLO GORDON ALFANO BOSICK &  
RASPANTI, LLP

One Oxford Centre, 38th Floor

Pittsburgh, PA 15219

412-263-1816 Telephone

412-263-4246 Facsimile

[cct@pietragallo.com](mailto:cct@pietragallo.com)

*Attorney for Mylan Pharmaceuticals Inc.*

**CERTIFICATE OF SERVICE**

I certify that on the 29th day of October, 2020, I served the foregoing document on Plaintiffs' Co-Lead and Liaison Counsel via electronic mail.

*s/ Clem C. Trischler*